



U. S. Department of Justice
Drug Enforcement Administration
Office of Training
P.O. Box 1475
Quantico, Virginia 22134-1475

AM | 2

Mr. Steve Mays
Manager, Regulatory Affairs
Amerisource Bergen
P.O. Box 959
Valley Forge, Pennsylvania 19482

Dear Mr. Mays:

This letter is to confirm previous arrangements made by the Drug Enforcement Administration (DEA) Office of Training Acting Unit Chief Tom Prevoznik for a tour of the Bergen Brunswig facility in Richmond, Virginia, by our Diversion Investigator Trainees. I appreciate your cooperation, and I am certain that the visit to your distribution plant will be a valuable learning experience for our students.

The visit to Bergen Brunswig is scheduled for Wednesday, March 9, 2005. Approximately 40 employees participating in the tour will be arriving by bus at approximately 9 a. m., and we will depart your facility at approximately 12 noon for the return trip to Quantico, Virginia.

Again, thank you for your cooperation and support of the DEA Office of Training. Mr. Prevoznik will be in contact with you regarding further arrangements. In the meantime, if you should have any questions, please do not hesitate to contact him at (703) 632-5217.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. McCarty".

John R. McCarty
Special Agent in Charge

AM-WV-00786

Pharmaceutical Wholesale Drug Industry Regulatory Compliance

Presented by AmerisourceBergen Corporation in
cooperation with the Drug Enforcement Administration



Chris Zimmerman, CPP, CFE

Vice President

**Corporate Security and Regulatory
Affairs**

AmerisourceBergen Corporation

Valley Forge, PA



Statement of Goals

- The goal of this program is to provide the participants with an overview of the Pharmaceutical (Drug) Wholesale industry and the Wholesaler's compliance with 21 C.F.R. 1300 to the End. In addition, we will provide examples and methods of standard operating procedures of a full-line pharmaceutical wholesaler in an attempt to educate and thus enhance and build on the good working relationship between the Industry and DEA.

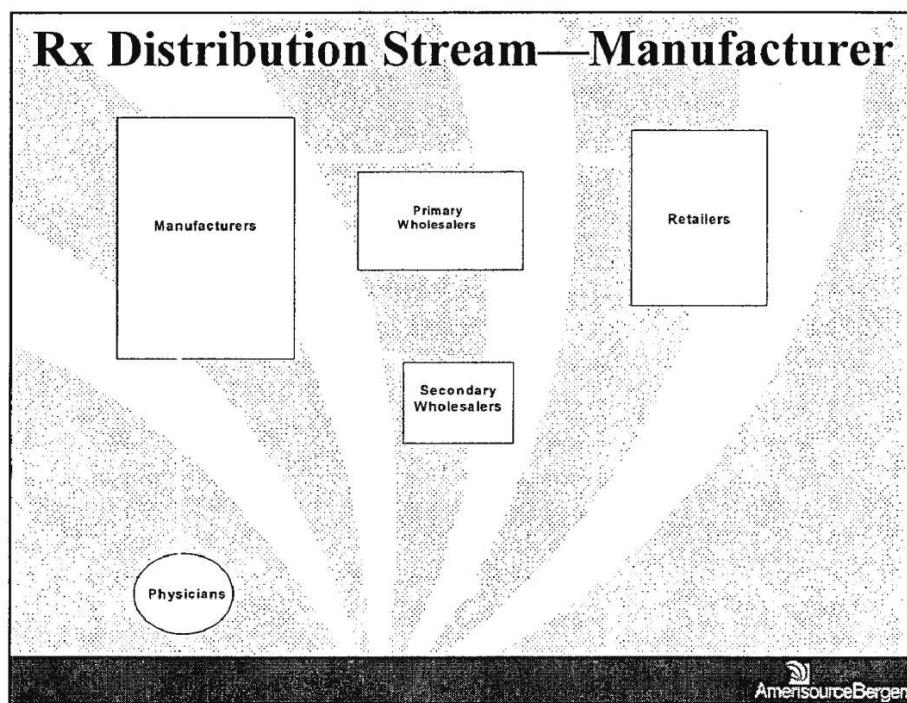
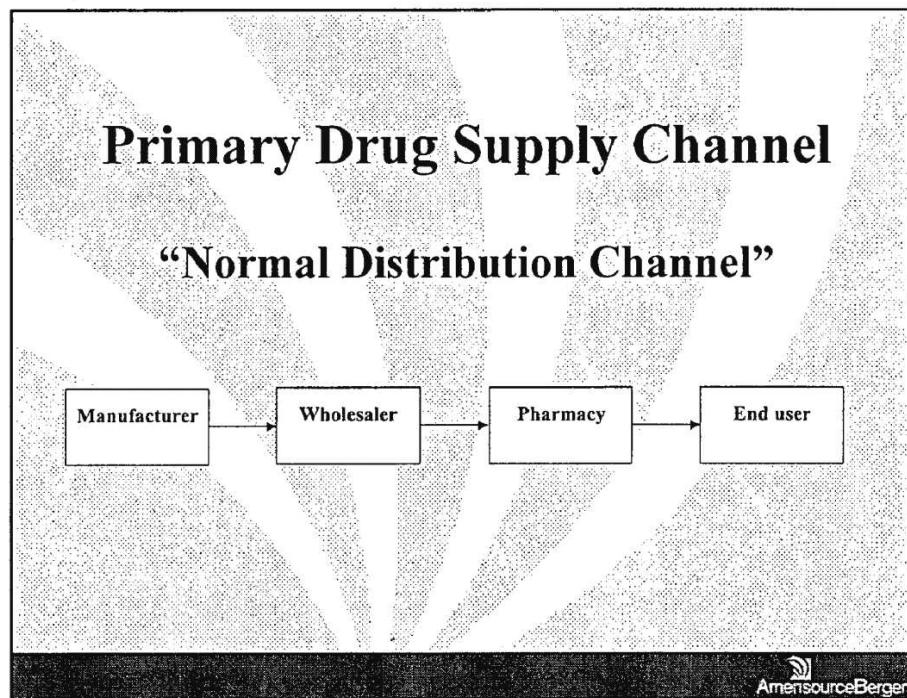


Objectives

At the end of the presentation attendees should:

- Understand the basic functions of a drug wholesaler with regard to distribution of controlled substances
- Be familiar with the basic structure and departments of a drug wholesaler
- Understand the Industry, basic operations and procedures and how they relate to 21 CFR 1300 to the end
- Evaluate and understand the different types of reports and documents available during an audit





Wholesaler Definitions

► Primary Wholesaler

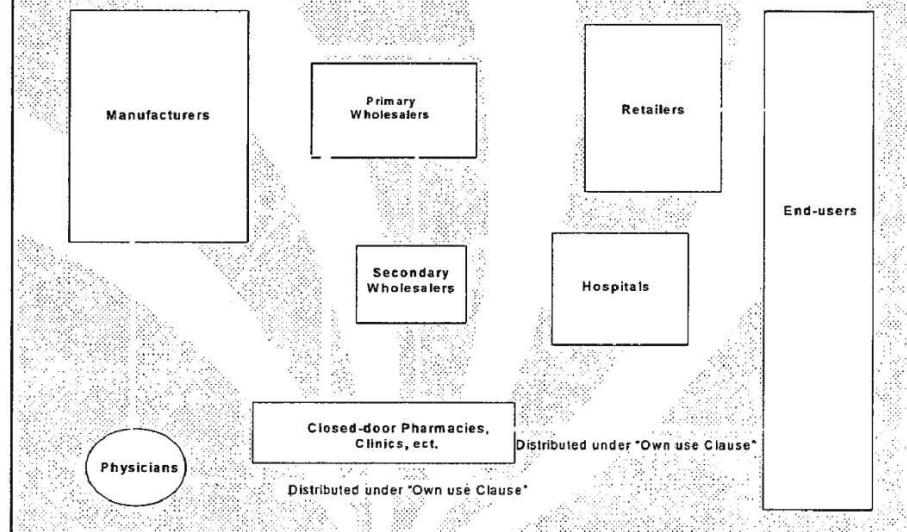
- Purchase majority of their products from the manufacturer
- Distribute the majority of their products to providers (Pharmacies, Hospitals, Clinics, etc.)
- Approximately 90% of all drugs distributed are through the "Big 3" (ABC, Cardinal Health, McKesson)

► Secondary Wholesalers (NMV's, ASV's)

- Purchase the majority of their products from other wholesalers
- Distribute the majority of their product primarily to other wholesalers
- There are approximately 7,000 licensed wholesalers in the United States (50 primary wholesalers)

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Rx Distribution Stream



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Wholesale Drug Distributors

- There are over 3,000 different manufacturers of pharmaceuticals and health care products in the United States
 - ABC maintains approximately 140,000 SKUs (stock keeping units)
- There are over 130,000 pharmacy sites in the U.S.
 - Retail
 - Closed Door
 - Hospital

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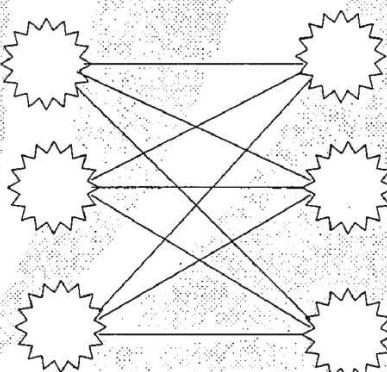
Role of the Wholesale Distributor

Without Distributors

Confusion and Complexity

If all 130,000 pharmacy sites ordered product from all 3,000 manufacturers once a month the industry would generate 4.9 billion transactions each year

Manufacturers Pharmacies



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Role of the Wholesale Distributor

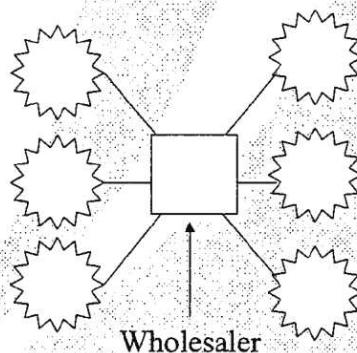
With Distributors

Control and Common Sense

Utilizing the 50 primary drug wholesalers that number is cut to 80 million transactions (99% reduction)

Manufacturers

Pharmacies



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Wholesale Drug Distributors

- There are approximately 50 primary wholesalers who operate approximately 230 distribution centers nationwide which generate approximately \$120 billion in sales annually
- The top 3 wholesalers account for approximately 90% of the market
- In the past decade the industry has cut operating expenses by over 30 percent
- Cutting operating expenses has not curbed the steady decline in profit margins
- Average product mark-up is 1%
- Estimated net profits for Wholesale Drug Distributors is less than 1 percent (0.65%) of sales

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Cost of Inadequate Compliance

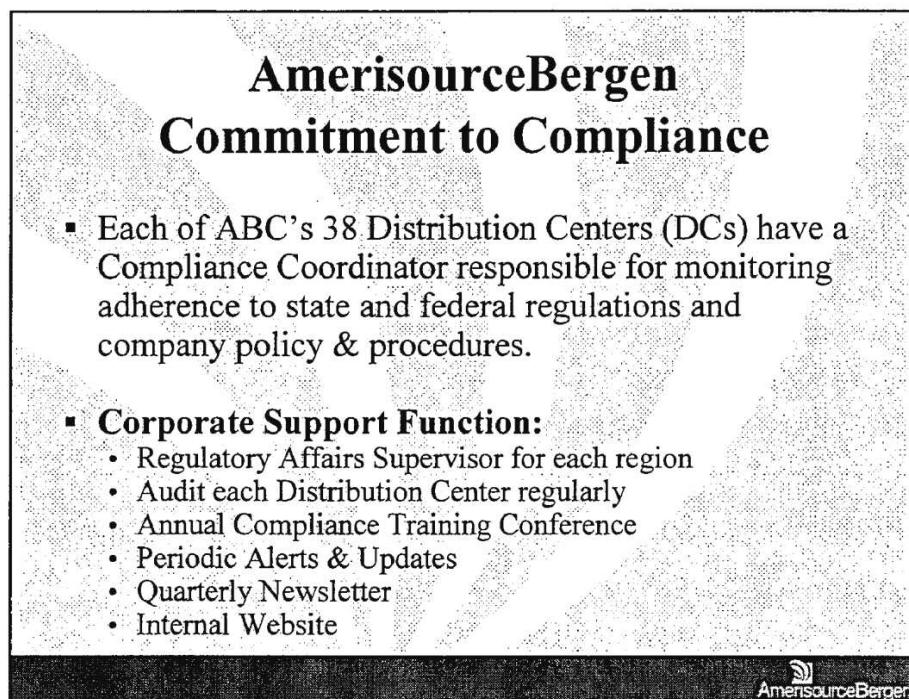
- Sales Dollars required to recover loss:
 - \$1,000 loss @ 1% profit margin would require approximately \$100, 000 in sales to recover the loss.
 - \$10,000 loss @ 1% profit margin would require approximately \$1,000, 000 in sales to recover the loss.
 - \$50,000 loss @ 1% profit margin would require approximately \$5,000, 000 in sales to recover the loss.



AmerisourceBergen Corporation

- AmerisourceBergen is one of the largest pharmaceutical services company in the United States. In addition to wholesale distribution, ABC is also a leader in the long term care pharmacy and workers' compensation fulfillment marketplaces.
- ABC has been in business since 1889
- ABC 2004 annualized revenue - \$47 billion
- Employs 14,000 people
- ABC is ranked #22 on the Fortune 500 list
- Operates 170 separate DEA registered locations
- ABC subsidiaries (ABDC, ABSG, ABPG, ABTG, Pharmerica,)





AmerisourceBergen Corporation - Microsoft Internet Explorer provided by AmerisourceBergen Corp.

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Address: http://myabc.amerisourcebergen.com/content/departments/csa/index.html

Search

Corporate Security & Regulatory Affairs

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Corporate Security & Regulatory Affairs

Welcome to the Corporate Security & Regulatory Affairs (CSRA) website, your source for regulatory and security information. Our mission is to "establish a culture of compliance within all operating companies that prioritizes education, prevention, detection, and resolution of instances of conduct that are not compliant with state and federal laws, regulatory agencies, and/or corporate policy and procedures; and to provide protection to company personnel, property, and the provision of a safe workplace."

In keeping with our mission, we are providing a comprehensive collection of documents, forms and informational links to assist you with your compliance effort.

News

- 06/03/2004 -- ALERT! CSRA has been advised by Pfizer and FDA that counterfeit Vigrx 100mg/30tab, Lot # 3023883, has recently appeared in the market place. [read more >>](#)
- 05/23/2004 -- ALERT! CSRA recommends that access cards do not include AmerisourceBergen or other identifiers, such as a return mail address, that could link the badge to a specific location. In lieu of AmerisourceBergen, it is suggested that the company logo be used without the name. [read more >>](#)
- 05/21/2004 -- NEW!! Corporate Security link! This link will be your source for Corporate Security specific documents. Currently contains the Watchlist, a "hotlist" for products most susceptible to theft. Check back later as we add additional content to this link! [read more >>](#)
- 05/12/2004 -- UPDATE! Bill to/Ship to Situations [read more >>](#)
- 04/30/2004 -- The 2004 Compliance Conference has concluded and you are back in your offices eager to put into practice all the valuable information you have received! For your convenience, we have added most of the presentations and handouts to our site as an easy reference. Please stop by often!! [read more >>](#)
- 04/19/2004 -- NEW!! ABC's "ARCOIS 2 User's Guide for STAR DC's" has been added to our site. [read more >>](#)

Links

- ABC Regulatory Compliance Program
- Alerts & Updates
- Anti-Diversion Program
- Corporate Security
- Forms/Templates/Instructions
- HIPAA Website
- Licensing & Registration
- Link to State & Federal Agencies
- Meetings/Conferences
- MSEA
- Online Forms
- Policy Manuals & Audit Checklists
- Product Safety Information
- The AmerisourceBergen Associate Portal
- Training

Department Information

- Contact CSRA
- CSRA Compliance Grid
- CSRA Organization Chart
- CSRA Today

AmerisourceBergen Commitment to Compliance

- Separation of Duties (Operations & Compliance) ensures the integrity of the program

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graph TD
    CEO[ABC Chief Executive Officer] --- GC[General Counsel]
    CEO --- Pres[President]
    GC --- Legal[Legal]
    GC --- RA[Regulatory Affairs]
    Pres --- Ops[Operations]
    Pres --- Sales[Sales]
    Pres --- Proc[Procurement]
  
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- "The Network" – A toll free anonymous reporting hotline.
(1.800.NETWORK)

AmerisourceBergen

AmerisourceBergen Drug Company

- DEA Audits/Inspections
 - Average approximately 12 audits each year
 - Each distribution center audited once every 3-5 years
- ABC Security and Regulatory Compliance Audits
 - Average approximately 30 audits each year
 - Each distribution center audited once every 6 - 18 months
- Other Regulatory Agencies Impacting Distribution
 - FDA (PDMA & New Food Handler Registration)
 - State Boards of Pharmacy/Departments of Health
 - Dept. of Transportation/FAA
 - OSHA
 - EPA (Rx Waste)
 - HIPAA (Patient Privacy)
 - Bureau of Wholesale Furniture



AmerisourceBergen Drug Company

- General Operational Time Line (six days/week)
 - Receiving (6:00am - 2:00pm)- approx. \$125-190 million daily
 - Ordering (6:00am - 9:00pm) - approx. 100 - 1,000 night Avg.
 - Picking (12:00pm - 3:00 am) - approx. 10K - 70K Lines Avg.
 - Shipping (10:00pm - 6:00am)
 - Delivery (7:00 am - 4:00pm)



Standardization

- ▼ All ABC DCs operate under the same procedures.
- ▼ ABC DC security systems & policies were developed to comply with Title 21 of the Code of Federal Regulations:
 - ◆ 21 CFR, Part 1300 – Storage & Distribution of Controlled Substances & Listed Chemicals
 - ◆ 21CFR, Part 200 – Storage & Distribution of pharmaceutical product (PDMA)



Code of Federal Regulations

- Interpretation
 - Between different facets of the Industry (Phcy, Dist, Mfg's)
 - Between Industry and DEA
 - Between DEA Field Offices and/or Washington



21 CFR 1301 - Security

- 1301.71 - provide effective controls to guard against theft and diversion (Internal/External)
 - Building Security
 - Physical Controls
 - Security Systems (alarm, access control, CCTV, etc.)
 - Segregated Areas (lobby, office, warehouse, parking)
 - Policy and Procedures
 - Employee entrance
 - Emergency exits monitored 24 hr by Alarm Company
 - Visitor log and badges
 - No packages (purses, backpacks, etc.) in warehouse
 - No picking aprons outside warehouse
 - Package Search Policy



21 CFR 1301 - Security

- 1301.72 - Physical Security Controls
 - Vault & Cage
 - Physical
 - construction (concrete, modular, wire gauge)
 - security systems (different detection sensors)
 - Policy and Procedures
 - Access lists
 - Shipping and Receiving policies (DBL check, log)
 - Inventory control
 - Accountability is key



21 CFR 1301 - Security

- 1301.74 - Other Security Controls
 - Good faith inquiry
 - VERY IMPORTANT FUNCTION
 - Wholesale distributors have an express duty to verify licensure and registration status of its customers
 - Customer File Set Up
 - on-site customer inspection
 - retain copy of each customer's current registration prior to shipment of any CS or Listed Chemical products
 - DEA information entered into computer system exactly as represented on actual registration certificate
 - only delivery to address in system as printed on order form and/or registration



21 CFR 1301 - Security

- Customer File Maintenance
- Customer DEA Review Report (NTIS)
 - reviewed monthly by each distribution center
 - also reviewed by CSRA
- Federal Register review daily
- 30 and 60 day expiration reports printed at distribution centers
- License expiration notifications printed on invoices
- Computer system automatically "blocks" orders of CS & LC from customers with expired registrations
- Computer system automatically "blocks" schedules of CS & LC from customers not authorized



21 CFR 1301 - Security

- 1301.74 - Other security controls
 - Suspicious order reporting system
 - Suspicious orders include orders of unusual size, deviating substantially from a normal pattern, and/or unusual frequency
 - Automated reporting system (daily fax to DEA)
 - Flexible reporting timeframes (daily, weekly, monthly)
 - Customer specific (retail, hospital, physician, etc.)



21 CFR 1301 - Security

- 1301.74 - Other security controls
 - Theft/loss reporting (DEA Form 106)
 - Common and contract carriers
 - ABC Selection & Evaluation Checklist/Inspection
 - Narcotic Treatment Center deliveries
 - Authorized signatures on file



21 CFR 1301 - Security

- 1301.90 & .93 - Employee Screening
 - Prospective employees including temporary associates
- All Associates
 - "Justifacts" - ALL felony & misdemeanor convictions
 - Drug Screens – Initial and Random
- "Compliance Critical" Personnel
 - DEA - Drug related charges, denials, revocations, etc.
 - Annual "Justifacts" criminal record checks



21 CFR 1304 – Records & Reports

- 1304.04 - Maintenance of records and inventories
 - 2 years (3 years maintained per PDMA guidelines)
 - Central Recordkeeping
 - not including executed DEA Form 222's or inventories
 - Records must be made available within two business days of a written request
 - Schedule II records must be stored separately
 - Schedule III-V records stored separately or in a readily retrievable manner



21 CFR 1304 – Records & Reports

- 1304.11 - Inventory requirements
 - Complete and accurate record of all controlled substances on hand on the date the inventory is taken
 - ABC Policy and Procedures regarding shipping, receiving and returns and accurate dates
 - Inventories
 - Daily activity counts (detect and correct errors)
 - Monthly inventory of all Controlled Substances on hand in the building (saleable & unsaleable)
 - Year End ARCOS - Schedule II & III narcotics (Dec. 31st COB)
 - Two complete physical inventories of all product annually.
 - Biennial - a complete inventory within two years of Initial or last Biennial inventory (ABC - Dec. 31st every even-numbered year)



21 CFR 1304 – Records & Reports

- Area of confusion during audits/inspections
- 1304.22 - Records for distributors
 - Product name, description, quantity, name, addresses, DEA registration number, for all transactions (sales, receipt, credit, debit, etc.)
 - ABC Invoice & Credit Memo (See samples)
 - All of this information is available
- 1304.33 Reports to ARCOS
 - Filed monthly
 - All Schedule II and Schedule III narcotic products



21 CFR 1305 - Order Forms

- 1305.03, .06, .09 & .11 - An order form (DEA Form 222) is required for each distribution of a Schedule II controlled substance
 - Alterations, incomplete forms
 - Each DEA Form 222 is double-checked and matched against work order for accuracy and completeness
- 1305.07 - Power of Attorney
 - Authorizes other associates to sign DEA Form 222's
- 1305.15 - Cancellations
 - Purchaser cancellations
 - Supplier cancellations
- Automation (CSOS) will positively impact the Industry



21 CFR 1309 – Listed Chemicals

- Registration, Recordkeeping and Reporting
- 1309.21 - (Registration) Every person who distributes List I Chemicals shall obtain annually a registration specific to List I Chemicals....
 - Exemptions
 - DEA Controlled Substance registration
 - “retail distributor”
- 1309.23 - Separate registration for separate locations
 - System automatically blocks customers without registration



21 CFR 1310 – Listed Chemicals

- 1310.03 - (Recordkeeping) Required Records
 - Regulated transactions
- 1310.04 - Maintenance of Records
 - Regular business records are acceptable
 - Current plus 2 years
 - Central location record retention acceptable
 - “Readily Retrievable”

*Inventories of Listed Chemicals



21 CFR 1310 – Listed Chemicals

- 1310.05 - (Reporting) Required Reports
 - Extraordinary quantity
 - Uncommon method of payment or delivery
 - Excessive loss or disappearance
- Reporting requirements for Chemicals are different than Controlled Substances
 - Oral notification upon discovery of loss
 - Written report must be filed within 15 days of oral notification
 - No DEA Form 106



Future Issues Impacting Drug Wholesalers

- Crime
 - Theft/Burglary
 - Counterfeit Product
- Controlled Substance Ordering System (CSOS)
- Listed Chemicals Storage Requirements
- Rescheduling of certain products



Questions ?

- Pharmaceutical Distribution Industry
- AmerisourceBergen Corporation
- Registration
- Security
- Records and Reports
- Order Forms
- Listed Chemicals

